IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

LISA ZAYAS, CATALINA OCAMPO, and DEBORAH JEAN, individually and on behalf of all others similarly situated, Plaintiffs, v. EDGEWELL PERSONAL CARE COMPANY, EDGEWELL PERSONAL CARE BRANDS, LLC, EDGEWELL PERSONAL CARE, LLC, PLAYTEX PRODUCTS, LLC, SUN PHARMACEUTICALS, LLC; Defendants.	Case No. 4:21-cv-00797-SRC **MEMORANDUM IN SUPPORT OF MOTION TO DISMISS**

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Other Authorities

DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED CLASS ACTION COMPLAINT AND INCORPORATED MEMORANDUM OF LAW

Defendants Edgewell Personal Care Company, Edgewell Personal Care Brands, LLC, Edgewell Personal Care, LLC, Playtex Products, LLC, and Sun Pharmaceuticals, LLC (collectively, "Defendants") respectfully submit this Memorandum in Support of their Motion to Dismiss the putative First Amended Class Action Complaint ("FAC") (Dkt. #19) filed by Plaintiffs Lisa Zayas, Catalina Ocampo, and Deborah Jean ("Plaintiffs") pursuant to Federal Rules of Civil Procedure 8, 9(b), 12(b)(1), and 12(b)(6). For all of the reasons set forth below, this Court should dismiss Plaintiffs' FAC with prejudice because the defects in Plaintiffs' FAC – including that Plaintiffs lack standing, Plaintiffs' claims are preempted by federal law, Plaintiffs fail to satisfy the reasonable consumer standard, and Plaintiffs' further failure to state a claim for relief – are fatal to Plaintiffs' claims.

INTRODUCTION

Plaintiffs allege Defendants[1] fraudulently marketed their Banana Boat® sunscreen products, via product labels and a single 2016 Safety Data Sheet.[2] [3] (the "Products" are defined in fn. 2). Plaintiffs claim Defendants failed to disclose trace amounts of benzene in the Products. *See* FAC ¶¶ 23, 25-27. Plaintiffs base their claims solely on testing purportedly performed by a third-party pharmacy, Valisure, and the citizen petition Valisure filed with the Food and Drug Administration

[1] Not all Defendants are involved in the manufacture and sale of the products at issue. Defendants reserve the right to challenge, if necessary, the real party in interest.

[2] Plaintiffs identify the following Banana Boat® brand sunscreens as the "Products:" Deep Tanning Dry Oil Clear Sunscreen Spray SPF 4; Kids Max Protect & Play™ Sunscreen C-Spray SPF 100; Kids Mineral Based Sunscreen Lotion SPF 50+; Kids Sport Sunscreen Lotion Spray SPF 50; Protective Dry Oil Clear Sunscreen Spray with Coconut Oil SPF 15; Simply Protect™ Kids Sunscreen Spray SPF 50+; Simply Protect™ Sensitive Mineral Enriched Sunscreen Lotion Spray SPF 50; Ultra Defense® Ultra Mist® Clear Sunscreen Spray SPF 100; Ultra Sport™ Clear Sunscreen Spray SPF 100; Ultra Sport™ Sunscreen Lotion SPF 100; Ultra Sport™ Clear Sunscreen Spray SPF 30; and Ultra Sport™ Clear Sunscreen Spray SPF 50 (hereinafter, the "Products"). FAC ¶ 18.

[3] Plaintiffs fail to allege which "Banana Boat[®] brand sunscreen" product they actually purchased. *See* FAC ¶¶ 7-9.

("FDA"). *See* FAC ¶¶ 19, 20.[4] Third-party Valisure alleges that some of the Products contain trace amounts of benzene. *See id*; Valisure Citizen Petition.

The Court should dismiss Plaintiffs' FAC for the following reasons:

First, Plaintiffs lack Article III standing. Plaintiffs have no "concrete and particularized injury" because they fail to allege that the products they purchased contained benzene. Plaintiffs merely allege that there is a "risk the products may contain benzene" because a third-party tested 19 bottles of Banana Boat® sunscreen products and found 5 of them purportedly contained benzene at levels of 0.43 ppm, or less, which is well below the FDA's 2 ppm benzene standard.

Second, Plaintiffs fail to state a claim for relief because a significant portion of the consuming population would not believe that a product label that complies with the FDA requirements is misleading.

Third, Plaintiffs fail to meet the heightened pleading requirement of Rule 9(b). Plaintiffs fail to identify which Products they purchased and articulate how and why the cited Safety Data Sheet is misleading.

Fourth, the Plaintiffs fail to state a claim under the state consumer protection statutes because Plaintiffs fail to allege they suffered an ascertainable loss.

Fifth, Plaintiffs' equitable claims fail because they fail to allege that they lack an adequate remedy at law.

---

[4] Valisure's Citizen Petition on Benzene in Sunscreen and After-sun Care Products, Valisure, LLC, May 24, 2021, https://www.valisure.com/wp-content/uploads/Valisure-Citizen-Petition-on-Benzene-in-Sunscreen-and-After-sun-Care-Products-v9.7.pdf and Valisure's Citizen Petition on Benzene in Sunscreen and After-sun Care Products Attachement A, Valisure, LLC, May 24, 2021, Attachment A https://www.valisure.com/wp-content/uploads/Attachment-A-Table-5-of-Valisure-FDA-Citizen-Petition-on-Sunscreen-v2.pdf (hereinafter "Valisure Citizen Petition") are attached as Exhibit B, Declaration of Megan McCurdy. On a Rule 12(b)(6) motion, courts may consider "matters incorporated by reference or integral to the claim . . . without converting the motion into one for summary judgment." *Miller v. Redwood Toxicology Lab'y, Inc.*, 688 F.3d 928, 931 (8th Cir. 2012) (citing 5B Wright & Miller, Fed. Prac. & Proc. § 1357 (3d ed. 2004).

Finally, Plaintiffs' claims are preempted by the Food Drug and Cosmetic Act ("FDCA") which authorizes the Food and Drug Administration ("FDA") to regulate, *inter alia*, the ingredients and labeling of nonprescription over-the-counter ("OTC") drugs, including "safety" and "efficacy" of the sunscreen Products at issue here. *See* 21 U.S.C. §§ 351, 352.21; 21 C.F.R. § 201, *et seq*.

For these reasons, the Court should dismiss all of Plaintiffs' claims with prejudice.

ARGUMENT

Plaintiffs filed this putative class action complaint alleging purported violations of Missouri's Merchandising Practices Act ("MMPA"), Mo. Rev. Stat. § 407.010, *et seq*.; Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("PUTPCP"), 73 Pa. Cons. Stat. §§ 201-1, *et seq*.; Illinois's Consumer Fraud Act ("ICFA"), 815 ILCS 505/1, *et seq*.; Oregon's Unlawful Trade Practices Act ("OUTPA"), Or. Rev. Stat. § 646.607, *et seq*.; fraudulent concealment; and unjust enrichment.

On May 25, 2021, Valisure filed its Citizen Petition with the FDA alleging that it tested select sunscreen products from various manufacturers and found trace amounts of benzene, ranging from zero and less than 0.1 ppm to 6.77 ppm. Valisure Citizen Petition and Att. A. The Banana Boat® Products tested well below FDA's standard – 2 ppm – for trace amounts of benzene, with amounts ranging from zero and less than 0.1 ppm to 0.43 ppm. *Id*. [5] Despite testing well below FDA standards for benzene, Plaintiffs now allege that the Products are "adulterated and misbranded" because the Product labels do not indicate that they may contain benzene as an ingredient. *See* FAC ¶¶ 23, 25-27. Plaintiffs state that they "would not have purchased Defendants' sunscreen products had [they] known

[5] Valisure tested 19 bottles of Banana Boat® sunscreen products. *See* Valisure Citizen Petition and Attachment A. "[B]enzene was not detected" in ten of the bottles. *Id*. at Att. A. Four Banana Boat® products tested at "<0.1" which is the lower limit of quantitation ("LLOQ"). *Id*. That is, four bottles tested less than the lowest amount a sample could be quantitatively determined to contain benzene. *Id*. at p 9. 14-15. Valisure represents that the following bottles contained benzene (in parts per million): Kids Max Protect & Play™ Sunscreen C – Spray SPF 100 at 0.11 ppm; Ultra Sport™ Clear Sunscreen Spray SPF 100 at 0.15 ppm; Kids Max Protect & Play™ Sunscreen C – Spray SPF 100 at 0.19 ppm; Ultra Mist® Deep Tanning Dry Oil Continuous Clear Spray SPF 4 at 0.36 ppm; and Kids Max Protect & Play™ Sunscreen C –SPF 100 at 0.41 and/or 0.43 ppm.

there was a *risk* the products *may* contain benzene." *See* FAC ¶¶ 7-9 (emphasis added).

Plaintiffs, however, do not identify the specific Banana Boat® sunscreen products they purchased, nor do they claim the products they purchased contained benzene. *Id*. Plaintiffs rely heavily on the Valisure Citizen Petition, but fail to acknowledge that 14 of the 19 Banana Boat® tested products had zero benzene or tested lower than less than the 0.1 ppm LLOQ. And the remaining results were well below the FDA's 2 ppm standard. Valisure Citizen Petition at pp. 13-15 and Att. A.

Plaintiffs also allege that a Safety Data Sheet, published by Edgewell Personal Care, LLC, on March 2, 2016 related to "Banana Boat® Dry Oil Spray SPF 4 (Aerosol)" and "Banana Boat® Sport Performance SPF 100 Sunscreen (Aerosol)" that states, "[t]his product is safe for its intended use based on the formulation, testing results, and the long history of safe consumer use," is "false and misleading." *See* Safety Data Sheet, EDGEWELL PERSONAL CARE, LLC (March 2, 2016) (https://edgewell.com/wp-content/uploads/2016/08/92014320-BB-Dry-Oil-Spray-SPF-4.pdf). FAC ¶ 23. However, neither of the products referenced in the Safety Data Sheet are included in the Products identified by Plaintiffs as allegedly containing benzene. Nor were these products referenced in the Valisure report. *See* Valisure Citizen Petition. Plaintiffs further fail to allege that they read or relied on the Safety Data Sheet.

I. PLAINTIFFS LACK STANDING REQUIRING DISMISSAL.

The Court should dismiss Plaintiffs' claims because the Court lacks subject matter jurisdiction. FED. R. CIV. P. 12(b)(1). Article III of the United States Constitution dictates that jurisdiction of the federal courts extends only to actual cases or controversies. U.S. Const. art. III; *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 590 (1992). To have standing under Article III of the U.S. Constitution, a plaintiff has the burden to show: (1) an injury-in-fact; (2) that the injury is traceable to the challenged action of the defendant; and (3) that the injury is redressable by a favorable ruling. *Lujan*, 504 U.S. at 560–61. *See also Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2752 (2010); and *Friends*

of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc., 528 U.S. 167, 180-81 (2000). "A defendant can challenge subject matter jurisdiction facially or factually." *Savage v. Fastnacht*, No. 05-1270-CV, 2007 WL 9733990, at *2 (W.D. Mo. Nov. 6, 2007).

A. PLAINTIFFS FAIL TO ALLEGE A PARTICULARIZED INJURY-IN-FACT THAT IS NOT HYPOTHETICAL OR SPECULATIVE.

Plaintiffs fail to allege an injury-in-fact required for standing under Article III. The Supreme Court has held that a plaintiff must suffer an injury that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560; *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1545 (2016); and *Friends of the Earth*, 528 U.S. at 180 (2000). Where a complaint makes allegations of potential future injury, the threat of future harm must be "certainly impending" as opposed to a mere possibility. *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990); *Lujan*, 504 U.S. at 564.

Courts have repeatedly found that plaintiffs do not plausibly allege an injury when they allege that ***some but not all*** products in a product line contain an offending substance and fail to allege that the product ***they purchased*** contained such substance. "It is not enough for a plaintiff to allege that a product line contains a defect or that a product is at risk of manifesting this defect; rather, the plaintiffs must allege that *their* product *actually exhibited the alleged defect*." *Wallace v. ConAgra Foods, Inc.*, 747 F.3d 1025, 1030 (8th Cir. 2014) (quotations omitted) (plaintiffs lacked standing because they "fail[ed] to show that any of the particular packages of [hotdogs] they personally purchased contained non-kosher beef"); *O'Neil v. Simplicity, Inc.*, 574 F.3d 501, 503 (8th Cir. 2009) (plaintiffs in a class action premised on a faulty crib lacked standing because they had not alleged that the cribs they purchased actually exhibited the defect likely to cause injury); *In re Polaris Mktg., Sales Practices, and Prod. Liab. Litig.*, ---F.4th---, 2021 WL 3612758, at *3 (8th Cir. 2021) (holding that some plaintiffs in a product liability class action lacked standing because they had not alleged their product actually exhibited the defect observed in other vehicles); *Briehl v. Gen. Motors Corp.*, 172 F.3d 623 (8th Cir.

1999) (holding that plaintiffs in a class action premised on faulty automatic brakes lacked standing because "at no time have the brakes exhibited a defect."); *Coffelt v. Kroger Co.*, No. 16-1471 JGB, 2018 WL 6004543, at *11 (C.D. Cal. Aug. 17, 2018) (plaintiff lacked standing when he failed to show the product he purchased had in fact been adulterated or contaminated and instead only alleged that the product "*may* have been contaminated"). For example, a plaintiff must "plead the water *he* purchased contained violative arsenic levels," not just that a report identified arsenic in some of the products. *Pels v. Keurig Dr. Pepper, Inc.*, No. 19-CV-03052-SI, 2019 WL 5813422 (N.D. Cal. Nov. 7, 2019) (dismissing plaintiff's claims that relied on consumer test reports to claim the product contained arsenic for lack of standing).

Further, economic injury cannot be premised on a hypothetical risk of harm. *In re Polaris*, 2021 WL 3612758, at *3 (affirming dismissal for lack of standing when plaintiffs failed to allege that their vehicles had exhibited the defect in question and thus, they did not allege a sufficiently particularized or concrete economic injury). Nor can it be premised on a speculative and uncertain risk of harm. *See, e.g.*, *Herrington v. Johnson & Johnson Consumer Cos., Inc.*, No. C 09-1597 CW, 2010 WL 3448531, at *3-5 (N.D. Cal. Sept. 1, 2010) (dismissing claims premised on allegations that products contained some amount of a substance that may be carcinogenic was "too speculative and uncertain" and failed to "establish a credible risk of harm that could suffice as a concrete, imminent injury"); *Boysen v. Walgreen Co.*, No. C 11-06262 SI, 2012 WL 2953069, at *5-7 (N.D. Cal. July 19, 2012) (acknowledging that the alleged level of toxins fell "within the FDA advisory guideline" and finding the alleged economic injury insufficient to establish standing when plaintiff alleged the product contained harmful toxins but failed to "expressly allege that the levels of lead and arsenic contained in defendant's juices are likely to cause physical harm").

Here, Plaintiffs do not allege the Products they purchased contained benzene. FAC ¶¶ 7-9. Instead, Plaintiffs make conjectural and hypothetical allegations that the Products "***may*** be adulterated

with benzene" and that "there was a ***risk*** the products ***may*** contain benzene." *Id.* (emphasis added). Plaintiffs' conjectural and hypothetical claims rely entirely on the Valisure Citizen Petition, and Plaintiffs fail to acknowledge that 14 of the 19 Banana Boat® tested Products had zero benzene or tested lower than less than the .1 ppm LLOQ. And the remaining results were well below the FDA's 2 ppm standard. Valisure Citizen Petition at 13-15 and Att. A.

Not only do Plaintiffs fail to allege they purchased Products that contain benzene, they also fail to allege that the Products they purchased were the same kind, were in the same product line, or were in the same lot as the 5 bottles that Valisure identified as containing trace amounts of benzene. *Compare* FAC ¶¶ 7-9 *with* Valisure Citizen Petition at 13. Courts regularly dismiss claims, like Plaintiffs, that rely on third-party testing of an allegedly defective product to confer standing. *See e.g. In Gaminde v. Lang Pharma Nutrition, Inc.*, No. 1:18-cv-300, 2019 WL 1338724, *3-4 (N.D.N.Y. Mar. 25, 2019) (plaintiff lacked standing because he "failed to allege that he tested his bottle of CVS Krill Oil" and "it is speculation to allege that because two CVS Krill Oil bottles in a USDA study were found to have less than the stated amount of Omega-3 Krill Oil, the bottle that [plaintiff] purchased must as well"); *Doss v. Gen. Mills, Inc.*, No. 18-61924-CIV, 2019 WL 7946028, *2 (S.D. Fla. June 14, 2019), *aff'd*, 816 F. App'x 312 (11th Cir. 2020) (plaintiff lacked standing because she did not "allege that the Cheerios she herself bought actually contain any glyphosate—just that some Cheerios that have been tested do"). Here, Plaintiffs failed to specifically identify the products they purchased contained benzene, leaving them only with a conjectural and hypothetical allegation that the products "may" contain benzene.

Further, Plaintiffs do not allege they suffered any physical harm from any alleged benzene in their products. Nor do Plaintiffs allege that the products they purchased failed to protect them from the sun. Instead, Plaintiffs allege they were economically injured because they "would not have purchased Defendants' sunscreen products had [they] known there was a ***risk*** the products ***may*** contain benzene."

FAC ¶¶ 7-9. This alleged economic injury is premised on the hypothetical and conjectural risk that Plaintiffs' Products are at ***risk*** of ***maybe*** containing benzene. Further, the only reason a Product would be worthless is if such trace amount of benzene is actually dangerous or could cause harm to Plaintiffs in the future. Even if Plaintiffs were to allege they purchased Defendants' Products containing trace benzene, Plaintiffs fail to allege that such trace amount of benzene would be dangerous or cause any harm. *See* Valisure Citizen Petition at 13. Defendants' Products tested well below the FDA's standard that allows for 2 ppm in the Products.[6]

Accordingly, Plaintiffs' alleged injuries are premised entirely on conjectural and hypothetical risks that (1) the products they purchased contained trace amounts of benzene and (2) such trace amounts of benzene could possibly cause harm to them in the future. Plaintiffs fail to allege that the Products they purchased contain benzene and fail to allege an economic injury sufficient to establish an injury-in-fact, as required for standing under Article III. As such, this Court should grant Defendants' Motion to Dismiss.

B. PLAINTIFFS LACK STANDING TO SEEK AN INJUNCTION BECAUSE THEY ALLEGED THAT THE PRODUCT IS WORTHLESS, ELIMINATING ANY THREAT OF FUTURE HARM.

Plaintiffs lack standing to seek an injunction. "To seek injunctive relief, a plaintiff must show that he is under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury." *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1149 (2009). To establish standing, the plaintiff must, at the very least, allege that he/she intends to buy the product in the future in some form. *See, e.g., Webb v. Dr. Pepper Snapple Grp., Inc.*, No. 4:17-00624-CV-RK, 2018 WL 1955422, at *7–8 (W.D. Mo. Apr. 25, 2018); *Johnson v. Atkins Nutritionals, Inc.*, No. 2:16-CV-04213-MDH, 2017 WL

[6] *See infra* § III.A. discussing the FDA's applicable 2 ppm standard for benzene.

6420199, at *12 (W.D. Mo. Mar. 29, 2017); *In re Gen. Mills Glyphosate Litig.*, No. CV 16-2869 (MJD/BRT), 2017 WL 2983877, at *4 (D. Minn. July 12, 2017); and *Frankle v. Best Buy Stores, L.P.*, 609 F. Supp. 2d 841, 848 (D. Minn. 2009). And, as the Ninth Circuit has observed, a plaintiff who alleges that the product is "worthless" lacks standing because "a plaintiff certainly would not purchase a worthless product in the future." *Min Sook Shin v. Umeken USA, Inc.*, 773 F. App'x 373, 375 (9th Cir. 2019).

Here, Plaintiffs do not even allege that they might purchase Defendants' Products in the future. Plaintiffs repeatedly allege that Defendants' Products are worthless because of the risk that they could contain benzene. FAC ¶¶ 4, 29, 31, 120. Plaintiffs certainly would not purchase a product in the future if they deem it worthless. For this reason, too, Plaintiffs lack standing to seek injunctive relief.

II. PLAINTIFFS FAIL TO STATE A CLAIM.

Plaintiffs' claims should also be dismissed because they fail to state a claim upon which relief may be granted. FED. R. CIV. P. 12(b)(6). To survive a motion to dismiss, Plaintiffs must plead "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also* FED. R. CIV. P. 8; *Twombly*, 550 U.S. at 555 (Under Rule 8, a plaintiff's "obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. . . . Factual allegations must be enough to raise a right to relief above the speculative level.") (citations omitted). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 129 (citing *Twombly*, 550 U.S. at 556).

A. PLAINTIFFS' CLAIMS FAIL TO MEET THE REASONABLE CONSUMER STANDARD.

To state a claim for violation of the ICFA, MMPA, OUTPA, or PUTPCP, the Plaintiffs must

demonstrate (among other things) that the defendant engaged in deceptive conduct—*i.e.*, conduct that would mislead a reasonable consumer. *See Barbara's Sales, Inc. v. Intel Corp.*, 879 N.E.2d 910, 927 (Ill. 2007) (ICFA); Mo. Rev. Stat. § 407.025.1 (MMPA); *Pearson v. Philip Morris, Inc.*, 361 P.3d 3, 33 n.26 (Or. 2015) (OUTPA); and *State v. Golden Gate Nat'l Senior Care LLC*, 194 A.3d 1010, 1024 (Pa. 2018) (PUTPCP).

In a clear effort to rein in the exploitation of the MMPA[7], the Missouri Legislature added a "reasonable consumer" standard to the MMPA. *See* Mo. Rev. Stat. § 407.025.1(a)-(b) (2020). The MMPA now requires plaintiffs to establish that they "acted as a reasonable consumer would in light of all circumstances" and that the alleged deceptive conduct "would cause a reasonable person to enter into the transaction . . . ." If not, the statute explicitly provides that a "court may dismiss [plaintiffs'] claim as a matter of law." Mo. Rev. Stat. § 407.025.1(b), 2(c).

[7] The Missouri Legislature passed Missouri Senate Bill 591 ("SB 591") to rein in claims under the MMPA, such as Plaintiffs' claims in this case. *See* 2020 Mo. Legis. Serv. S.B. 591 (2020) (effective August 28, 2020). In a clear effort to reduce exploitation of the previously broad language in the MMPA, SB 591 includes significant reforms to the MMPA that became effective on August 28, 2020. *See* Mo. Rev. Stat. § 407.025.1 (2020). When signing SB 591 into law, Missouri Governor Michael Parson stated that it would "stop the unfair and unreasonable litigation our businesses face" and "restore[] integrity in the Missouri Merchandising Practices Act." Press Release, Missouri Governor, Governor Parson Signs SB 591 Regarding Punitive Damages and Unlawful Merchandising Practices, (July 1, 2020) (accessed at https://governor.mo.gov/press-releases/archive/governor-parson-signs-sb-591-regarding-punitive-damages-and-unlawful).

Between 2000-2009, there was a 678% increase in reported MMPA decisions. *See* Joanna Shepherd, The Expanding Missouri Merchandizing Practices Act, 13 Am. Tort Reform Found. (2014). Punitive damages continued to run wild. *See* Lewellen v. Franklin, 441 S.W.3d 136 (Mo. banc 2014) (holding that a statutory cap on punitive damages violated an individual's constitutional right to trial by jury and reinstating a $1 million punitive damage award on plaintiff's misrepresentation claims as it related to her purchase of a used car). Missouri made Washington Post headline news, "A man is suing Hershey for 'under-filling' his box of Whoppers," Abha Bhattarai, A Man is Suing Hershey for 'Under-Filling' His Box of Whoppers, Wash. Post, May 25, 2017, available at https://www.washingtonpost.com/news/business/wp/2017/05/25/a-man-is-suing-hershey-for-under-filling-his-box-of-whoppers/ (last visited Oct. 22, 2020.). A federal judge denied defendant's motion to dismiss, holding that plaintiff plausibly stated a claim, *see Bratton v. Hershey Co.*, 2017 WL 2126864, at *9 (W.D. Mo. May 16, 2017), only to dismiss the case on summary judgment following two years of expensive litigation, *see Bratton*, 2018 WL 934899, at *5 (W.D. Mo. Feb. 16, 2018).

Plaintiffs' claims under the OUTPA, are evaluated under "an objective standard of what a reasonable consumer would understand the representation to be." *Pearson*, 361 P.3d at 33 n.26. Whether conduct is deceptive is measured by whether it is likely to cause confusion or misunderstanding in an ordinary buyer. *Knit Pearl, LLC v. Shibui, LLC*, No. CV-05-845, 2006 WL 8458984, at *13 (D. Or. Oct. 17, 2006). Under the ICFA, there must be a reasonable likelihood of deception. *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 938 (7th Cir. 2001). And under the PUTPCP, conduct must be likely to create confusion or misunderstanding. *Gregg v. Ameriprise Financial Inc.*, 245 A.3d 637, 650-51 (Pa. 2021). The "reasonable consumer" standard requires more than a mere possibility that a label "might conceivably be misunderstood by some consumers viewing it in an unreasonable manner." *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir. 2016). Rather, it requires a probability "that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." *Id.*

Courts routinely reject fraud-based challenges to products that contain trace amounts of residual solvents (like benzene) and pesticides within the FDA's tolerance levels under the reasonable consumer standard. *See, e.g., Young v. Johnson & Johnson*, No. 11-4580, 2012 WL 1372286, at *3 (D. N.J. Apr. 19, 2012) (dismissing consumer fraud action for failure to satisfy the reasonable consumer standard when plaintiff's claims were premised on failure to list trans fats in nutrient labeling and the FDA had expressly authorized seller to not list that ingredient in quantities less than 0.5g per serving).[8]

[8] *See also Hawyuan Yu v. Dr. Pepper Snapple Grp., Inc.*, No. 18-CV-06664-BLF, 2020 WL 5910071, at *4-7 (N.D. Cal. Oct. 6, 2020) (holding that reasonable consumer would not understand "all natural" to mean that the product did not contain trace amounts of pesticides below the limit tolerated by the FDA); *Axon v. Citrus World, Inc.*, 354 F. Supp. 3d 170, 183 (E.D.N.Y. 2018), aff'd sub nom. *Axon v. Florida's Nat. Growers, Inc.*, 813 F. App'x 701 (2d Cir. 2020) ("[T]he court finds it 'implausible that a reasonable consumer would believe that a product labeled ['Florida's Natural'] could not contain a trace amount of glyphosate that is far below the amount' deemed tolerable by the FDA," particularly given that (like benzene) "[g]lyphosate [] is not an 'ingredient' added to defendant's products; rather, it is a substance introduced through the growing process.");

Here, Plaintiffs appear to allege two theories of deceptive and misleading conduct: (1) omission of benzene as an ingredient and the omission of a warning that the Products may contain benzene; and (2) affirmative misrepresentations. Both fail to satisfy the reasonable consumer standard.

1. Plaintiffs' omission theory fails to satisfy the reasonable consumer standard.

Plaintiffs allege that the Products are false and misleading because the labels do not list benzene as an active or inactive ingredient on the product. *See e.g.* FAC ¶¶ 19, 24. Plaintiffs interpret the listed ingredients to mean that the Products are free from any trace of any other substances or residual solvents such as benzene. *Id.* In other words, Plaintiffs believe that the Products' listed ingredients contain absolute molecular purity and that it is misleading to not list trace amounts of benzene – well below the FDA's 2 ppm standard – as an ingredient that may be in the Products.

As discussed above, benzene is not an active or inactive ingredient in the Products. *See infra* § III.A. A significant portion of the general consuming public would not believe the Products could never contain trace amounts of a substance outside of the listed ingredients, especially when the FDA allows up to 2 ppm of residual solvents such as benzene. Nor would a significant portion of the general consuming public believe that the Products should list benzene as an ingredient when the FDA dictates exactly what "ingredients" must be included on the label. It is also implausible that a reasonable consumer would understand the products to be free of any trace amounts of benzene when the products are not labeled "benzene free." *See* Tobias Decl. at ¶¶ 6,7, Exhibit A.

Parks v. Ainsworth Pet Nutrition, LLC, 377 F. Supp. 3d 241, 247 (S.D.N.Y. 2019) ("But a reasonable consumer would not be so absolutist as to require that 'natural' means there is no glyphosate, even an accidental and innocuous amount, in the Products."); *In re Gen. Mills Glyphosate Litig.*, 2017 WL 2983877, at *6 ("[I]t is not plausible to allege that the statement 'Made with 100% Natural Whole Grain Oats' means that there is no trace glyphosate in Nature Valley Products or that a reasonable consumer would so interpret the label."); *see also Bush v. WellPet, LLC*, No. CV 21-10059-RGS, 2021 WL 1408118, at *3 (D. Mass. Apr. 14, 2021) (holding that any misrepresentation was immaterial because "[a] reasonable consumer therefore would not be so 'absolutist' as to require a 'grain free' product to contain no gluten, however negligible the amount actually present.").

Here, 14 of the 19 bottles tested by Valisure had zero and less than 0.1 ppm of benzene. *See* Valisure Citizen Petition at pp. 13-15 and Att. A. It is implausible that a reasonable consumer, acting reasonably under the circumstances would likely understand or be misled to believe that the Products are unsafe when they contain levels of benzene ***well under*** 2 ppm, which is deemed an "acceptable amount" for "safety" by the FDA. Nor would they expect the label to include a warning that the products may contain less than 2 ppm of benzene when the FDA specifically allows for up to 2 ppm of benzene in the Products. *See infra* § III.A.2. (discussing ICH 3). Further, a reasonable consumer would not understand or be misled to believe that their product is not effective because 5 bottles of sunscreen contained trace amounts of benzene. Indeed, Plaintiffs have failed to even allege that .43 ppm or less benzene would render the Products ineffective at protecting one from the sun.

2. Plaintiffs' misrepresentation theories fail to satisfy the reasonable consumer standard.

Further, no reasonable consumer would be misled by the alleged affirmative misrepresentations in Defendants' "advertising." Plaintiffs take statements out of context. Defendant Edgewell Personal Care, LLC published a Safety Data Sheet on March 2, 2016 related to "Banana Boat® Dry Oil Spray SPF 4 (Aerosol)" and "Banana Boat® Sport Performance SPF 100 Sunscreen (Aerosol)" that states: "[t]his product is safe for its intended use based on the formulation, testing results, and the long history of safe consumer use." *Safety Data Sheet,* Edgewell Personal Care, LLC (March 2, 2016) (https://edgewell.com/wp-content/uploads/2016/08/92014320-BB-Dry-Oil-Spray-SPF-4.pdf). Neither of these Banana Boat® products are included in Plaintiffs' definition of the Products. Nor do Plaintiffs allege they purchased either of these products.

It is further implausible that a significant portion of the population would rely on a March 2, 2016 online data sheet for the proposition that the products do not contain trace amounts of benzene when purchasing the Products. It is unreasonable that a significant portion of the consuming population would go online, come across a 2016 Safety Data Sheet, read the Safety Data Sheet, understand it to

mean that any and all Banana Boat® products would never contain less than 2 ppm of benzene, and then buy different Products in reliance on such understanding. This theory of deception is simply implausible. Accordingly, no reasonable consumer would be misled by the Safety Data Sheet in the manner Plaintiffs allege. Indeed, Plaintiffs do not even allege they read the safety data sheet. This is precisely the kind of claim that should be dismissed for failure to state a claim as a matter of law.

B. PLAINTIFFS FAIL TO MEET RULE 9(B)'S HEIGHTENED PLEADING STANDARD.

Where, as here, the claims are "grounded in fraud," the pleading must satisfy the particularity requirement of Rule 9(b), which requires Plaintiffs to "state with particularity the circumstances constituting fraud." *E-Shops Corp. v. U.S. Bank Nat'l Ass'n*, 678 F.3d 659, 663 (8th Cir. 2012). The complaint must identify "the time, place, contents of false representations, as well as the identity of the person making the misrepresentation and what was obtained or given there," or, in other words, "the who, what, when, where, and how" of the alleged misconduct. *Blake v. Career Educ. Corp.*, No. 4:08-CV-00821 ERW, 2009 WL 140742, at *2 (E.D. Mo. Jan. 20, 2009) (internal quotations and citations omitted); *see also Miller v. Nestle Purina Petcare Co.*, No. 4:13-CV-283-HEA, 2014 WL 307271, at *3 (E.D. Mo. Jan. 28, 2014) (dismissing plaintiff's complaint that failed to "detail what misrepresentations were made, where the statements were made, to whom they were made, and why they were misleading, and how the alleged misrepresentations were made to plaintiff"). Conclusory allegations of the Defendants' allegedly fraudulent conduct is insufficient, and the pleading must "contain a higher degree of notice, enabling the defendant to respond specifically, at an early stage of the case, to potentially damaging allegations of immoral and criminal conduct." *Schaller Tel. Co. v. Golden Sky Sys., Inc.*, 298 F.3d 736, 746 (8th Cir. 2002) (internal citations omitted). Where the Court can infer no more than a "mere possibility of misconduct" in a complaint's factual allegations, it must be dismissed. *Martin v. Wm. Wrigley Jr. Co.*, 4:17-CV-00541-NKL, 2017 WL 4797530, at *1 (W.D. Mo. Oct. 24, 2017).

Here, Plaintiffs fail to identify what products they even purchased. *See* FAC ¶¶ 7-9 (merely stating that Plaintiffs purchased "Banana boat brand sunscreen products"). Plaintiffs fail to allege which line of products they purchased or even if they purchased one of the sunscreens identified in their definition of Products. Plaintiffs fail to allege whether they purchased lotion or spray. Plaintiffs fail to even allege what SPF they purchased. Accordingly, Plaintiffs have failed to allege whether or not the Products they purchased are in the same product line or product lots as the 5 bottles that contain trace amounts of benzene according to Valisure. Merely alleging purchase of "Banana boat brand sunscreen products" is wholly insufficient. Plaintiffs' allegations must provide Defendants with a higher degree of notice to enable defendants to specifically respond to the allegations. Accordingly, Plaintiffs' claims should be dismissed for failure to plead with particularity the circumstances of their purchase.

Plaintiffs' also fail to allege they viewed, read, or even heard about the 2016 Safety Data Sheet prior to purchasing the Products. Nor do they allege when or where they were exposed to such 2016 Safety Data Sheet. Plaintiffs fail to allege they relied on the statements in the 2016 Safety Data Sheet, let alone how or why they relied on such statements and how or why such statements deceived them. Further, Plaintiffs have not shown that the Products contained even trace amounts of benzene ***in 2016*** when the statement was written—much less that the Products identified in the 2016 Safety Data Sheet were not "safe for [their] intended use" based on the three benchmarks identified: "formulation, testing results, and [a] long history of safe consumer use." *See* Safety Data Sheet. Thus, Plaintiffs have not plausibly alleged that the 2016 Safety Data Sheet contains statements that are false or misleading.

Accordingly, Plaintiffs' claims related to marketing and advertising should be dismissed because Plaintiffs fail to meet the heightened pleading standard under Rule 9(b) to state a claim on this basis under the ICFA, MMPA, OUTPA, or PUTPCP and fraudulent concealment.

C. PLAINTIFFS FAIL TO ALLEGE THEY SUFFERED AN ASCERTAINABLE LOSS.

Plaintiffs also fail to allege that they suffered an "ascertainable loss of money or property" as required under the ICFA, MMPA, OUTPA, or PUTPCP. *See* Mo. Rev. Stat. § 407.025.1 (2020); 73 P.S. § 201–9.2(a); ORS 646.638(1); *Petty v. Chrysler Corp*., 799 N.E.2d 432, 439-440 (Ill. App. 2003). Further, under the new amendments to the MMPA, Plaintiffs in Missouri now must also establish "[i]ndividual damages "with sufficiently definitive and objective evidence to allow the loss to be calculated with a reasonably degree of certainty." Rev. Mo. Stat. § 407.025(1)(c). To survive a motion to dismiss, Plaintiffs must allege facts showing that they suffered a present, pecuniary loss. *See Grawitch v. Charter Commc'ns, Inc.*, 750 F.3d 956, 960 (8th Cir. 2014); *Browning v. Apex Physical Therapy, LLC*, 4:19-CV-02395-JAR, 2020 WL 1455738, at *2 (E.D. Mo. Mar. 25, 2020). Plaintiffs must allege sufficient logical and factual foundation for loss that is not speculative. *See Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007, 1013 (E.D. Mo. 2014); *Early v. Henry Thayer Co., Inc.*, 4:20-CV-1678 RLW, 2021 WL 3089025, at *14 (E.D. Mo. July 22, 2021)(finding plaintiff failed to allege an ascertainable loss for certain products because she failed to allege she purchased a "product containing an ingredient that was missing from the ingredients list on the label"); *Petty*, 799 N.E.2d at 439-440 (Ill. App. 2003) (affirming dismissal because plaintiff could only speculate as to actual damages and presented no proof of actual damages); *Grimes v. Enter. Leasing Co. of Philadelphia, LLC*, 105 A.3d 1188, 1192-93 (Pa. 2014).

Plaintiffs' conclusory allegations that they "suffered ascertainable loss" are insufficient to satisfy ascertainable loss. *See* FAC ¶ 64. They do not state what the value of the product was "as represented" or how much they actually lost. They conclude that the products are "worthless," but they never allege any facts to establish that the Products where ineffective for their intended use: to help prevent sunburn. *See* Tobias Decl. at ¶ 7(b). Indeed, the FDA has recognized the products as generally safe and effective. *See infra* § III.A. "In the absence of factual support for the plaintiffs' allegation of

damages, the Plaintiffs' FAC is insufficient to withstand a motion to dismiss under Rule 12(b)(6)." *Grawitch*, 750 F.3d at 960.

D. PLAINTIFFS' EQUITABLE CLAIMS FOR UNJUST ENRICHMENT AND REQUESTS FOR EQUITABLE RELIEF FAIL BECAUSE THEY FAIL TO ALLEGE THEY LACK AN ADEQUATE REMEDY AT LAW.

The Court should dismiss Plaintiffs' equitable claim for unjust enrichment because they fail to allege that they lack an adequate remedy at law. Equitable remedies are not available where there is an adequate legal remedy. *Smith v. Curators of Univ. of Missouri*, No. 17-4016-CV-C-WJE, 2017 WL 11492763, at *6 (W.D. Mo. Dec. 20, 2017); *O'Shea v. Mutual Life Ins. Co. of New York*, No. Civ.A 01-2505, 2002 WL 32348944, at *2-3 (E.D. Pa. Jan. 22, 2002); *Nesby v. Country Mut. Ins. Co.*, 805 N.E.2d 241, 243 (Ill. App. 2004); *Adkisson v. Dir. of Revenue*, 891 S.W.2d 131, 133 (Mo. 1995); *Ballard v. City of Creve Coeur*, 419 S.W.3d 109, 117 (Mo. Ct. App. 2013). *Am. Honda Motor Co., Inc. v. Motorcycle Info. Network, Inc.* 390 F. Supp. 2d 1170, 1178 (M.D. Fla. 2005) (dismissing unjust enrichment claim against defendant because adequate remedy existed at law under the FDUTPA). "It is a basic doctrine of equity jurisprudence that courts of equity should not act ... when the moving party has an adequate remedy at law." *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 844 (9th Cir. 2020).

Here, Plaintiffs seek injunctive relief and restitution in addition to compensatory, statutory, and punitive damages. *See* FAC at Prayer. Plaintiffs' unjust enrichment claim and their requests for equitable relief should therefore be dismissed for failure to allege that they lack an adequate remedy at law because they have an adequate remedy at law.

III. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW.

Plaintiffs' claims seeking labeling requirements different from or in addition to the FDA's labeling regulations, are expressly preempted. *See infra*, § III.B. Implied and/or conflict preemption arises here because Congress left no room for states to supplement the field of FDCA regulations. *See infra*, § III.A. The doctrines of express and implied preemption leave Plaintiffs with only a "narrow

gap" through which to escape preemption by the FDCA. *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quotations omitted). "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under [the U.S. Supreme Court's decision in] *Buckman*)." *Id.* (emphasis original).[9] As evidenced by the extensive regulation of the Products, dismissal is warranted here.

A. THE PRODUCTS ARE SUBJECT TO AND IN COMPLIANCE WITH THE 1999 SUNSCREEN MONOGRAPH

The FDCA authorizes the FDA to regulate, *inter alia*, the ingredients and labeling of nonprescription OTC drugs, including the sunscreen Products at issue here. *See* 21 U.S.C. §§ 351, 352.21; 21 C.F.R. § 201, *et seq.*[10] Plaintiffs admit "[t]he FDA regulates sunscreens to ensure they meet safety and effectiveness standards." FAC ¶ 22. The OTC sunscreen Products are deemed to be generally recognized as safe and effective if they are in conformity with the general requirements for

---

[9] For a thorough explanation of express and implied preemption, *see* generally *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776–77 (D. Minn. 2009) ("[T]o avoid being impliedly preempted under *Buckman*, a claim must rely on traditional state tort law which had predated the federal enactments in question. In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*").

[10] The FDA's overview of the "Over-the-Counter (OTC) Drug Monograph Process" provides:

In 1972, FDA established the OTC Drug Review to evaluate the safety and effectiveness of hundreds of thousands of OTC drug products that were on the market at that time. Under the OTC Drug Review, FDA regulates certain nonprescription drugs using a system that groups products by therapeutic category. For each category, FDA issues an OTC drug monograph (OTC monograph). An OTC monograph is a "rule book" for each therapeutic category establishing conditions, such as active ingredients, uses (indications), doses, labeling, and testing, under which an OTC drug is generally recognized as safe and effective (GRASE) and can be marketed without a New Drug Application and FDA pre-market approval.

Over-the-Counter (OTC) Drug Monograph Process, FDA, Sept. 3, 2020, available at https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process (last visited on August 27, 2021).

nonprescription drugs, the requirements specified in the 1999 Sunscreen Monograph,[11] the applicable requirements governing effectiveness and labeling in 21 C.F.R. § 201.327, and the general requirements for nonprescription drugs in 21 C.F.R. 330.1. *See* 21 U.S.C. § 355h(a). If the Products fail to meet such requirements, the Products are misbranded and subject to regulatory action. *See* U.S.C. § 352(ee); 21 C.F.R. § 330.1; 21 C.F.R. § 201.66.

1. The Products are not misbranded or adulterated because benzene is not an ingredient in the Products.

In the case at hand, benzene is neither an active nor an inactive ingredient. *See* Tobias Decl. at ¶ 7, Exhibit A. The FDCA requires active ingredients and inactive ingredients to be included on the label. *See* 21 U.S.C. § 352(e); 21 C.F.R. § 201.66(c). The FDA regulations define "active ingredient" as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals." 21 C.F.R. § 210.3 "Inactive ingredient" is defined to include any component that is not an active ingredient. *Id.* "Component" is any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product. *Id.* Benzene is not an active or inactive ingredient in the Products. It was not listed on the label and it was never intended for use in the manufacture of the drug products. Indeed, Plaintiffs acknowledge in their FAC that "benzene is used primarily as a solvent in the chemical and pharmaceutical industries, as a starting material and intermediate in the synthesis of numerous chemicals." FAC ¶ 21. Accordingly, the Products are not misbranded or adulterated as Plaintiffs contend.

[11] Part 352 of Title 21, Code of Federal Regulations, as published in the 1999 Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph (64 FR 27666 at 27687).

2. The Products are in compliance with the FDA standard that allows up to 2 ppm of benzene in the Products.

The FDA allows for trace amounts of benzene up to a concentration of 2 ppm.[12] Both General Chapter 467 and ICH Q3C allow up to 2 ppm of benzene residual solvents in the Products. *Id*. "The objective of [Q3C] guidance is to recommend acceptable amounts for residual solvents in pharmaceuticals for the safety of the patient. The guidance recommends use of less toxic solvents and describes levels considered to be toxicologically acceptable for some residual solvents" *See* ICH Q3C at 3. The Products' active ingredients are also subject to the 2 ppm standard in ICH QC3 and General Chapter 467. *See* 1999 Final Monograph, preamble. Further, the Product label must only identify benzene as a residual solvent on the packaging if the amount exceeds this 2 ppm concentration limit. *See* Residual Solvent Guidance.

All of the Banana Boat® products, tested by Valisure, had concentration limits of benzene well below 2 ppm, *see supra* footnote 5; which is the level accepted by FDA. Accordingly, the Products are not per se adulterated and the Products do not require benzene to be listed on the label.

B. PLAINTIFFS' CLAIMS ARE PREEMPTED

"The Supremacy Clause provides a clear rule that federal law 'shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012) (quoting U.S. const. art. VI, cl. 2). "Courts discern an intent to preempt state law when

[12] *See* FDA, "Residual Solvents in Drug Products Marketed in the United States" (2009) at nn 2, accessible at https://www.fda.gov/media/70928/download ("Residual Solvent Guidance") (applying standards in USP General Chapter 467 Residual Solvents, accessible at https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf ("General Chapter 467"); International Conference on Harmonisation guidance for industry Q3C Impurities: Residual Solvents (updated April 22, 2021), accessible at https://database.ich.org/sites/default/files/ICH_Q3C-R8_Guideline_Step4_2021_0422_1.pdf ("ICH Q3C").

Congress expressly forbids state regulation (express preemption), when it creates a scheme of federal regulation so pervasive that the only reasonable inference is that it meant to displace the states (field preemption), and when a law enacted by it directly conflicts with state law (conflict preemption). *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 886 (8th Cir. 2005)." Preemption may be either express or implied. *Missouri Bd. of Exam'rs for Hearing Instrument Specialists v. Hearing Help Exp., Inc.*, 447 F.3d 1033, 1035 (8th Cir. 2006). Here, Congress has unambiguously intended to expressly and impliedly preempt state law claims imposing labeling requirements differing from or in addition to those required by federal regulations.

1. Plaintiffs' claims are expressly preempted.

Plaintiffs' state law claims, if successful, would impose state law requirements that are expressly preempted under § 379r of the FDCA. Section 379r(a) provides that states may not establish "any requirement ... (1) that relates to the regulation of a [nonprescription drug]; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under [the FDCA]...." 21 U.S.C. § 379r(a). Plaintiffs' claims[13] that would impose labeling, testing, and warning requirements in addition to or different from requirements provided by the FDA are expressly preempted, as intended by Congress. *See Early*, 2021 WL 3089025, at *10 *(*dismissing plaintiffs' allegations that the products must include additional disclaimers and identify ingredients in a manner different than what was required by the FDA because "these requirements would be different from or in addition to what is required under the FDCA" are thus preempted); *Anglin v. Edgewell Personal Care Co.*, No. 4:18-cv-00639, 2018 WL 6434424, at *7 (E.D. Mo. Dec. 7, 2018) (dismissing plaintiffs' false advertising SPF claim because of plaintiffs' non-FDA complaint independent testing); *Dougherty v. Source Naturals, Inc.*, 148 F. Supp. 3d 831, 834 (E.D. Mo.

[13] Plaintiffs specifically seek relief for conduct that is expressly permitted by the FDA. *See* FAC at Prayer, ¶¶ B, G.

2015) (dismissing MMPA claim premised on mislabeled vitamin supplements because claim was preempted by FDA regulations that expressly permitted such labeling).

The FDA regulates the labeling requirements of the Products through 21 C.F.R. § 201.66 in conjunction with 21 C.F.R. § 201.237 and the 1999 Sunscreen Monograph provides labeling requirements related to directions and use, intended purpose, ingredients, disclosures, safety warnings, potential allergic reactions and when to discontinue use. *See* 21 C.F.R. 201.66(c); 1999 Sunscreen Monograph. *See also supra* § III.A. "The content and format requirements [of 21 C.F.R. 201.66] must be followed unless otherwise specifically provided in the applicable monograph or regulation." 21 C.F.R. § 201.66(a). "An OTC drug product that is not in compliance with the format and content requirements in this section is subject to regulatory action." 21 C.F.R. § 201.66(g).

21 C.F.R. § 201.66(c) requires that the label display certain warnings, if applicable, in the exact language quoted in the regulation. It further requires that the label indicate both active and inactive ingredients. 21 C.F.R. § 201.66(c). However, it does not provide for any deviation except for those outlined in the 1999 Sunscreen Monograph. *Id*. The only deviation permitted is related to non-misleading statements describing use and the "other information" permitted by the 1999 Sunscreen Monograph is limited to "protect the product in this container from excessive heat and direct sun." 21 C.F.R. § 201.237(c), (f). Generally, a manufacturer cannot unilaterally change its warning language and such deviations are subject to FDA enforcement action. *See* 21 C.F.R. § 330.1.

Here, Plaintiffs allege that the Products are misleading because they "fail[] to include labeling indicating to the consumers that the Sunscreen Products may contain benzene as an active or inactive ingredient." FAC ¶ 27; *see also* FAC ¶¶ 18, 23. Pursuant to the FDA as discussed *supra* § III.A.1., benzene is not an active or inactive ingredient in the Products and therefore, the Products

are not misbranded or adulterated for failure to include benzene as an ingredient or warning on the label. Defendants are not permitted to include any warnings on the Products that are not outlined in the 1999 Sunscreen Monograph, 21 CFR § 201.66(c), or 21 CFR § 201.237(d). See 21 CFR § 330.1. Further, a claim is not misleading if expressly permitted by the FDA. *See, e.g., Dougherty*, 148 F.Supp.3d at 834 (dismissing MMPA claim premised on mislabeled vitamin supplements because claim was preempted by FDA regulations that expressly permitted such labeling). As demonstrated above, the FDA allows for trace amounts of benzene up to a concentration of 2 ppm. *See supra* §§ III.A.2-B.1. Accordingly, Plaintiffs' proposed label changes are preempted by the FDA.

2. Plaintiffs' claims are also impliedly preempted.

Even though the FDCA contains an express preemption provision, such a provision does not foreclose the applicability of implied preemption as well. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287-89 (1995). "[A] federal statute implicitly overrides state law either when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively, or when state law is in actual conflict with federal law." *Id.* at 287 (internal citation omitted). Implied or conflict preemption arises when a state-law claim "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or a federal agency acting within the scope of its congressionally delegated authority. *Capital Cities Cable, Inc. v. Crisp*, 467 U.S. 691, 698-99 (1984) (citation omitted). The FDA's extensive and exclusive regulation of the Products, *see supra*, §§ III.A, further demonstrates that Congress left no room for states to supplement the field of FDCA regulations. As such, Plaintiffs' claims are impliedly preempted.

3. Plaintiffs' claims are barred as private enforcement actions.

Plaintiffs' claims are also preempted to the extent they challenge the Products' safety and efficacy and to the extent they claim the products are adulterated and misbranded because Plaintiffs

do not have a private right to allege FDCA violations. "[A]ll proceedings for the enforcement, or to restrain violations of [the Act] shall be by and in the name of the United States." 21 U.S.C.A. § 337; *see also Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 938 (8th Cir. 2011) (explaining that violations of the FDCA do not create private rights of action). Thus, the doctrines of express and implied preemption leave Plaintiffs with only a "narrow gap" through which to escape preemption by the FDCA. *Dougherty*, 148 F. Supp. 3d at 834 (plaintiff must sue for conduct that violates the FDCA, or else the claim is expressly preempted, but plaintiff must not sue because the conduct violates the FDCA as that claim is impliedly preempted).

Here, Plaintiffs allege the products are adulterated under Section 501 of the FDCA and misbranded under Section 502 of the FDCA. *See, e.g.*, FAC ¶¶ 19, 23-25, 49, 56, 60, 69. Plaintiffs also claim the products are not safe and effective, which is subject to the exclusive jurisdiction of the FDA. *See, e.g.*, FAC ¶¶ 9, 37. These claims are barred because Plaintiffs are not allowed to bring a private right of action to enforce the FDCA.

CONCLUSION

The Court should dismiss this action. Plaintiffs lack Article III standing because they allege an injury-in-fact that is hypothetical and speculative. Plaintiffs further fail to allege facts sufficient to satisfy standing for injunctive relief. No reasonable consumer would be misled in light of Defendants' compliance with the 2 ppm standard. Plaintiffs fail to meet the heightened pleading requirement of Rule 9(b) because they fail to allege what Products they purchased and fail to articulate the how and why the alleged advertising is misleading. And finally, Plaintiffs' claims are preempted by the FDCA. Any one of the foregoing arguments represents sufficient grounds to dismiss Plaintiffs' FAC with prejudice. Accordingly, the Court should dismiss this action.

Respectfully submitted,

STINSON LLP

By: */s/Megan McCurdy*

John W. Moticka, Mo. 31760
7700 Forsyth Boulevard, Suite 1100
St. Louis, Missouri 63105-1821
Telephone: (314) 863-0800
Facsimile: (314) 863-9388
john.moticka@stinson.com

Megan A. McCurdy, Mo. 60071
1201 Walnut Street, Suite 2900
Kansas City, Missouri, 64106
Telephone: (816) 842-8600
Facsimile: (816) 691-3495
megan.mccurdy@stinson.com

Ashley Crisafulli, Mo. 71852
1201 Walnut, Suite 2900
Kansas City, Missouri 64106
Telephone:816.691.2676
Facsimile: 816.412.9733
ashley.crisafulli@stinson.com

ATTORNEYS FOR ALL DEFENDANTS

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 30th day of August, 2021, the above and foregoing was filed with the Clerk of the Court through the CM/ECF system, which will send electronic notification to all counsel of record.

/s/Megan McCurdy
ATTORNEY FOR ALL DEFENDANTS